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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,317	07/18/2001	Betty P. Tsao	18810-82152	5671
34055	7590	03/18/2005	EXAMINER	
PERKINS COIE LLP			JOHANNSEN, DIANA B	
POST OFFICE BOX 1208			ART UNIT	
SEATTLE, WA 98111-1208			PAPER NUMBER	

1634

DATE MAILED: 03/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/909,317	Applicant(s) TSAO ET AL.	
	Examiner Diana B. Johannsen	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2004.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 12-19 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1-9 and 12-19 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1104</u> . | 6) <input type="checkbox"/> Other: _____ |

FINAL REJECTION

1. This action is responsive to the Amendment and Response of December 6, 2004 (which included a complying complete set of claims, as required by the Notice of November 15, 2004). Claims 1-2 and 12 have been amended, and claims 10-11 have been canceled. Claims 1-9 and 12-19 are now pending and under consideration. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims. **This action is FINAL.**
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

3. The use of the trademarks ABI PRISM, GENESCAN, GENOTYPER, and GENBANK in this application is again noted. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

4. Claims 9 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons set forth in the Office action of June 28, 2004.

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Specifically, claims 9 and 19 are indefinite over the recitation of the trademarks SYBR and YO-PRO in the claims. A trademark cannot be used properly to identify a particular material or product, but rather identifies a source or origin of a product (MPEP 2173.05(u)). As the actual product or material that corresponds to a trademark may change, the use of SYBR and YO-PRO in the claims renders the claims vague and indefinite. The response traverses the rejection on the grounds that the trademarks employed in the claims “are the only convenient means for identifying these dyes” and that the dyes “are well known and widely used in the art, making it unlikely that the product associated with these names will change,” and asserts that this is “illustrated in part by the fact that both of these names regularly appear in patent claim language,” citing several examples. These arguments have been thoroughly considered but are not persuasive. First, while it is acknowledged that the trademarks SYBR and YO-PRO do appear in the claims of several patents, this fact does not render definite the language as used in instant claims 9 and 19. Further, while applicant may be of the opinion that the products associated with these trademarks are “unlikely” to change, it is clearly possible that changes may in fact occur – for this reason, the trademarks cannot be relied upon to provide a definite description of the particular product employed by applicants at the time the claimed invention was made. Similarly, the fact that other modes of description for the products employed by applicant are less convenient than the trademarks SYBR and YO-PRO does not render the trademarks definite. Accordingly, this rejection is maintained.

Double Patenting

5. Claims 1-9 and 12-19 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,280,941 B1, for the reasons stated in the Office action of June 28, 2004. An obviousness type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). In the instant case, although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-9 and 12-19 of the instant application are generic to all that is recited in claims 1-4 of the '941 patent. That is, claims 1-4 of the '941 patent fall entirely within the scope of claims 1-9 and 12-19, or, in other words, claims 1-9 and 12-19 are anticipated by claims 1-4, respectively. In particular, it is noted that both sets of claims recite the steps of collecting tissue, amplifying nucleic acids, and detecting amplification products to identify SLE predisposition, and that the primers of '941 claims 1-4 are the same as those of instant dependent claims 5-7 and 15-17. Thus, claims 1-4 of the '941 patent anticipate instant claims 1-9 and 12-19.

The response traverses the rejection on the grounds the instant claims and those of the '941 patent differ in that the claims of the '941 patent require specific primers (SEQ ID Nos 1 and 2) and in that the method of the '941 patent uses only "size of the

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amplification products” to determine SLE predisposition. The response further urges that the claims of the instant application “identify SLE predisposition based on the nucleotide sequence of the amplification products.” Applicants’ arguments have been thoroughly considered but are not persuasive. First, it is again noted that the claims of the instant application (as acknowledged by Applicant in the Response) encompass the use of any primer set that amplifies the region between D1S2860 and D1S213; accordingly, the instant claims clearly encompass the use of SEQ ID Nos 1-2 as recited in the ‘941 patent claims (as further evidenced by the recitation of these sequences in the dependent claims of the instant application). Second, the instant claims merely require “detecting” in amplification products the presence or absence of particular CA repeat sequences; the claims do not, e.g., recite a particular method that must be employed to accomplish this detection (e.g., the claims do not require sequencing); thus, the claims are written are sufficiently broad so as to encompass any method of “detecting” the presence or absence of these repeat sequences, including detection based on product length. Accordingly, the claims of the instant application encompass methods having the exact method steps recited in the claims of the ‘941 patent, and the claims of the ‘941 patent therefore anticipate the instant claims, as stated in the prior Office action. Therefore, this rejection is maintained.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 571/272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, reading "Diana B. Johannsen". The signature is written in a cursive style with a large, stylized "D" and "J".

Diana B. Johannsen
Primary Examiner
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March 16, 2005